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# PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional): 2132.109

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on 7-31-2006

Signature

Typed or printed name: Debra N. Gerstemeier

| Application Number | Filed |
|---|---|
| 09/991,796 | 11/23/2001 |

First Named Inventor: George Jackowski

| Art Unit | Examiner |
|---|---|
| 1649 | Olga N. Chernyshev |

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- ☐ applicant/inventor.
- ☐ assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- ☑ attorney or agent of record. Registration number 43,377
- ☐ attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____

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7/31/2006
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NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☐ *Total of _____ forms are submitted.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

| | |
|---|---|
| APPLICANT | : Jackowski et al. |
| INVENTION | : **Fibronectin Biopolymer Markers Indicative of Type II Diabetes** |
| SERIAL NUMBER | : 09/991,796 |
| FILING DATE | : November 23, 2001 |
| EXAMINER | : Chernyshev, Olga N. |
| GROUP ART UNIT | : 1649 |
| OUR FILE NO. | : 2132.109 |

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CERTIFICATE UNDER 37 CFR §1.8(a)
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**PRE-APPEAL BRIEF REQUEST FOR REVIEW**

Sir:

Claim 1, as presented on February 9, 2006, stands finally rejected (Final Rejection dated March 16, 2006), under both 35 USC 101 and 35 USC 112, first paragraph.

***Claim 1. An isolated biopolymer marker which evidences a link to Type II diabetes selected from the group consisting of SEQ ID NO:1 and SEQ ID NO:4.***

The novelty of the biopolymer markers designated SEQ ID NOS: 1 and 4, has been established during examination. The alleged lack of a disclosed specific and substantial credible utility has thus far prevented claim 1 from being deemed patentable.

The Examiner has maintained rejections under 35 USC 101 because "the claimed invention is drawn to an invention with no apparent or disclosed specific and substantial credible utility" and under 35 USC 112 (paragraph 1) because, absent either a clear asserted utility or a

well established utility, one skilled in the art "clearly would not know how to use the claimed invention".

Applicants respectfully submit that the rejections under 35 USC 101 and 35 USC 112, 1st paragraph, are clearly in error, are improper and are untenable.

In most cases, an Applicant's assertion of utility creates a presumption of utility that will be sufficient to satisfy 35 U.S.C. § 101. As the CCPA stated in In re Langer:

As a matter of Patent Office practice, a specification which contains a disclosure of utility which corresponds in scope to the subject matter sought to be patented must be taken as sufficient to satisfy the utility requirement of § 101 for the entire claimed subject matter unless there is a reason for one skilled in the art to question the objective truth of the statement of utility or its scope. 503 F.2d 1380, 1391 (CCPA 1974).

Compliance with § 101 is a question of fact. Raytheon, 724 F.2d at 956. Examiners must present countervailing facts and reasoning sufficient to establish that a person of ordinary skill would not believe the applicant's assertion of utility. In re Brana, 51 F.3d 1560 (Fed. Cir. 1995).

The MPEP clearly states that where an applicant has specifically asserted that an invention has a particular utility, that assertion cannot be dismissed as being "wrong", even when there may be reason to believe that the assertion is not entirely accurate. MPEP § 2107.02. Rather, the Examiner must determine whether the assertion of utility is *credible* - i.e., whether the assertion of utility is believable to any person of ordinary skill in the art based on the totality of evidence and reasoning provided. An assertion is credible unless A) the logic underlying the assertion is seriously flawed, or B) the facts upon which the assertion is based are inconsistent with the logic underlying the assertion. Id.

To properly reject a claimed invention under § 101, the Examiner must A) make a *prima facie* showing that the claimed invention lacks utility, and B) provide a sufficient evidentiary basis for factual assumptions relied upon in establishing the *prima facie* showing. In re Gaubert, 524 F.2d 1222, 1224 (CCPA 1975). Otherwise, a rejection under § 101 should not be imposed. *See, e.g.,* In re Oetiker, 977 F.2d 1443, 1445 (Fed. Cir. 1992). Rejections under § 101 have rarely been sustained by the courts, unless the applicant failed to disclose any utility for the invention or asserted a utility that could only be true if it violated a scientific principle, or was

wholly inconsistent with contemporary knowledge in the art. In re Gazave, 379 F.2d 973, 978 (CCPA 1967).

It is important to remember that if an applicant makes one credible assertion of utility, utility for the claimed invention as a whole is established. An applicant need only make one credible assertion of specific utility for the claimed invention to satisfy 35 U.S.C. § 101 and 35 U.S.C. § 112. Additional statements of utility, even if not credible, do not render the claimed invention lacking in utility. *See, e.g.,* Raytheon, 724 F.2d at 958 ("When a properly claimed invention meets at least one stated objective, utility under 35 U.S.C. § 101 is clearly shown.").

The Examiner has failed to meet the legal requirements for maintaining the rejections under 35 U.S.C. § 101 and 35 U.S.C. § 112. In order for a rejection under 35 USC 101 to be appropriate the Examiner must demonstrate that there is a complete absence of data supporting the statements which set forth the desired results of the claimed invention (*In re Joyce A. Cortright* 49 USPQ 2d 1464 1999).

It is respectfully submitted that the "link to Type II diabetes" asserted by Applicants, was elucidated under real world conditions according to a methodology as set forth in the following steps:

I) isolating peptides from body fluid samples obtained from two groups of patients,

a) one group known to suffer from Type II diabetes; and

b) a group of healthy controls;

II) carrying out the protocols disclosed in the specification (see pages 37-47);

III) comparing the expression pattern of protein bands from the two groups of patients as evidenced in gels (such as that in Figure 1);

IV) subjecting the noted expression pattern to the criteria as disclosed at page 11, lines 9-20 of the instant specification;

V) excising bands that were differentially expressed between the two groups, and, submitting the peptides present within the excised bands for sequence identification by mass spectrometry.

The instant inventors, using the above described methodology in a real-world environment, thereby elucidated and identified SEQ ID NOS: 1 and 4 as fragments of fibronectin precursor proteins found in healthy control patients but absent in patients having Type II

diabetes, thus establishing the instantly claimed link to Type II diabetes evidenced by the observed differential expression.

The mass spectral profiles indicative of these peptides are disclosed in Figures 2 and 4 (SEQ ID NO:1 in Figure 2 and SEQ ID NO:4 in Figure). Mass spectral profiles are reproducible, and are typically published for reference purposes.

Thus, any skilled artisan, in a real-world context, and without significant further research, could utilize the mass spectral profiles provided in the instant specification as references for comparing with mass spectral profiles of peptides obtained from an unknown sample to test the unknown sample for a link to Type II diabetes, thereby establishing a disclosed specific and substantial credible utility.

However, although the Examiner does not dispute the fact that the claimed peptides are differentially expressed, the Examiner does not find their use as markers linked to Type II diabetes to be credible.

As evidenced by the above discussion, the instant specification clearly provides data (Figures 1-4) which sets forth the use of the claimed peptides as markers linked to Type II diabetes.

Furthermore, as set forth in *Raytheon Company v. Roper Corporation,*(220 USPQ 592 1983), if an invention meets at least one stated utility, utility as a whole is established. The instant invention clearly meets the objective, stated in the specification as originally filed at page 35, lines 14-18, of evaluating samples containing a plurality of biopolymers for the presence of a biopolymer marker which evidences a link to at least one specific disease state.

Additionally, in contrast to the holding in Fisher (*In re Fisher* 76 USPQ 2d 1225 2005), where EST's were deemed not to have a substantial and credible utility, the instantly claimed peptides do indeed evidence a specific use as markers linked to Type II diabetes supported by data specifically directed to patients having Type II diabetes.

In contradistinction to the Examiner's remarks at page 11, the last paragraph of the Final rejection, the instant invention meets the Fisher test of disclosure of a substantially utility by showing that an invention is useful to the public as disclosed in its current form, not that it may be useful at some future date after further research, and thus a significant and presently available benefit to the public is disclosed.

With regard to the credibility of Applicants' showing, precedent dictates that a holding of lack of credibility by an Examiner can only be made if the Examiner has reason to doubt the objective truth of the statements contained in the written description (*In re Joyce A. Cortright* 49 USPQ 2d 1464 1999). In the instant situation, the Examiner does not appear to doubt Applicants' statements, and in fact, in the paragraph bridging pages 8-9 of the Final Rejection, the statement is made that "the Examiner does not doubt or dispute the results of differential expression of the instant claimed peptides of SEQ ID NO. 1 AND 4."

In view of this statement, and further in conjunction with the fact that the Examiner has failed to present any countervailing facts and reasoning sufficient to establish that a person of ordinary skill in the art would not believe the Applicants' assertion of utility (*In re Brana* 34 USPQ 2d1436 1995), it is respectfully submitted that credible utility has been established.

In light of the foregoing remarks, Applicants respectfully submit that the Examiner has failed to meet the burden of establishing a *prima facie* case for lack of substantial and credible utility.

Lastly, with respect to the rejection under 35 USC 112, 1st paragraph, a skilled artisan could easily follow the methodology for elucidating the presence of peptides of SEQ ID NO: 1 AND 4, as disclosed in the patent application (and reiterated *supra),* on a non-differentiated patient population, in order to discern members of the population who manifest Type II diabetes.

## ***CONCLUSION***

It is respectfully submitted that the outstanding rejections of claim 1 under 35 USC 101 and 35 USC 112, first paragraph is clearly in error. It is therefore requested that these grounds of rejection be withdrawn and the case passed to issue.

Respectfully submitted,

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